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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,407	01/02/2002	Abraham Pinter	07763-048002	8341
26161	7590	12/16/2003	EXAMINER	
FISH & RICHARDSON PC			PARK, HANKYEL	
225 FRANKLIN ST			ART UNIT	PAPER NUMBER
BOSTON, MA 02110			1648	13

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/038,407	PINTER, ABRAHAM	
	Examiner Hankye T. Park	Art Unit 1648	
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>23 September 2003</u> .			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .                    2b) <input checked="" type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-32</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input checked="" type="checkbox"/> Claim(s) <u>2-17,19,20 and 27-32</u> is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>18 and 21-26</u> is/are rejected.			
7) <input checked="" type="checkbox"/> Claim(s) <u>1</u> is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
12) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
13) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
14) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .		6) <input type="checkbox"/> Other: _____ .	

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## **DETAILED ACTION**

1. Applicant's submission of the "Reply to Action of March 24, 2003" and the Declaration filed on 9/23/03, Paper Nos. 11 and 12, respectively, is acknowledged.
2. Claims 1-32 are pending and examined.
3. The rejection under 35 U.S.C. 103(a) is withdrawn in view of the Applicant's persuasive argument and the Declaration that the cited reference is not a proper reference under 35 U.S.C. 103(a).

### ***Claim Objections***

4. Claim 1 is objected to because of the following informality: Claim 1 in line 4 recites "neutralized." It should be "neutralizes" as in the rest of the claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "administering" a mammalian subject with a composition comprising the protein of claim 1, does not reasonably provide enablement for "immunizing" a mammalian subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these

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claims. It is well known in the art of HIV that there is no known method as of today for “immunizing” a mammalian subject against an HIV infection, lacking any evidence to the contrary.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “capable of” because it is not clear whether a protein actually elicits an antibody (Claim 18) or whether the antibodies actually neutralize infection (Claim 21).

9. Claims 1-32 are deemed to distinguish over the prior art.

10. Claims 18 and 21-26 are not allowed.

11. Claim 1 is objected to because of a minor informality.

12. Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hankyel T. Park, Ph.D., whose telephone number is (703) 305-7255. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Wednesdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Hankyel T. Park

December 13, 2003



HANKYEL T. PARK, PH.D.  
PRIMARY EXAMINER